Dissolution Tester with Heater
DT light Series – DH 1520

Instruction Manual

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Instruction Manual
Dissolution Tester with Heater
DT light Series – DH 1520

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1 – Introduction

Thank you for purchasing the ERWEKA dissolution tester of DT light series with DH 1520.

1.1 – About this instruction manual

This instruction manual supports you in work with your ERWEKA device. It describes the device, its operation and gives you useful tips on its handling. Furthermore, read descriptions of installation and setting as well as detailed step-by-step work operations in the present manual. Pictures facilitate the understanding of processes described here.

Storage

Read this manual completely before using the device and make sure you understand its content. The instruction manual is a part of the product. Keep this manual in a safe place so that it will be available for any questions at a later date. This is important for long-term and efficient function of the corresponding device.

Further applicable documents

Use an external temperature sensor PT 100 to operate the device. Please also read the instruction manuals for the components that you will be using together with the device described here.

Feedback

The editorial team of ERWEKA appreciates your feedback regarding the present manual. Just send an e-mail to *quality@erweka.com* with your topic and “technical documentation” as a subject. Your feedback will also help us to meet our high quality requirements.

Gender awareness

We designate groups of persons in a neutral form (e.g. skilled personnel) for reasons of easier readability. This should by no means express gender discrimination or violation of the principle of equality.

1.2 – Service

Contact ERWEKA at *support@erweka.com* to order the spare parts, in case of technical questions or possible repairs. Please supply the following information:

- Type of the device (on the type label)
- Serial number of the device (on the type label)
- Short description of the case

1.3 – Hints and symbols of this manual

The following hints and symbols are used in the following instruction manual.

WARNING indicates a possible hazardous situation which, if not avoided, could result in death or serious injury.

CAUTION indicates a possible hazardous situation which, if not avoided, could result in moderate or minor injury.

HAZARD of electric shock! Indicates a possible hazardous situation which, if not avoided, can lead to injuries caused by electric shock.

NOTICE This symbol indicates a possible hazardous situation which, if not avoided, can lead to equipment damage.

This notice indicates a possibly hazardous situation. Information from the instruction of the product mentioned in the text is required at this point in order to proceed further. Pay attention to the safety precautions listed there.

This symbol indicates information that will ensure smooth work processes.

This symbol provides you with additional useful information.

The following text markings are used in this instruction manual.

1.	Numbered enumerations indicate a sequence of action steps.
→	Arrows indicate device reactions or consequences of actions.
SMALL CAPS	Text formatted in this way displays an operation/control element (UI, display, softkey, etc.).
SMALL CAPS BOLD	Text formatted in this way displays the element to be used at this point.

2 – Safety and Environment

2.1 – Safety information

To guarantee the health and safety, read the following safety instructions before using the device.

WARNING
Danger when handling media!
Wear personal protective gear and safety glasses when necessary. Observe safety regulations for work in laboratories.

HAZARD of electric shock!
Electric devices are to be plugged into safety sockets only. Use the delivered power cable. The voltage of the existing current supply is to be compared to the indications on the type label. Before installation works always switch the corresponding device off and disconnect it from the rear panel.

NOTICE Damage due to operator error. ERWEKA devices should be operated by qualified and trained personnel only.

Pay attention to the on-site safety instructions for work in the laboratory and with the laboratory equipment!

2.2 – Protection of the environment

This device is supplied with antifreeze liquid with Tyfocor® L (mixing ratio Tyfocor® L : water = 1 : 4). Spilt or leaked antifreeze liquid should be absorbed and discarded according to regulations. The current product safety data sheet Tyfocor® L contains further information. This can be requested from the manufacturer.

Note that product residues must be properly disposed of in accordance with the respective valid environmental legislation.

According to the valid EU directives all the electrical parts (electrical scrap) must be disposed of appropriately.

2.3 – Intended use

The ERWEKA dissolution tester of DT light series should be used only for performing dissolution tests, associated verification and quality control of tablets, dragees, oblongs and other formulations.

The requirements for installation environment defined by ERWEKA shall be met.

The device should be operated and maintained only as intended and in accordance with the instructions presented in this manual.

2.4 – Foreseeable misuse

Set-up and operation of the device in potentially explosive atmospheres (Ex areas) is not permitted.

ERWEKA devices should not be used for processing:

- Products that are easely flammable or explosive
- Products that develop vapours which may create flammable or explosive mixtures in combination with air
- Products that release harmful or poisonous substances

2.5 – High-risk area

During a test, the stirring shafts with stirring elements execute a defined stirring movement.

Attention, unintentional stopping of the stirring shafts may result in incorrect test results. Do not reach into this area during a test. Wear clothes with tight-fitting sleeves. Tie back long hair. Do not wear any ties, long necklaces, bracelets or scarves. Only trained and authorised personnel should operate this device.

2.6 – Warning notes on the device

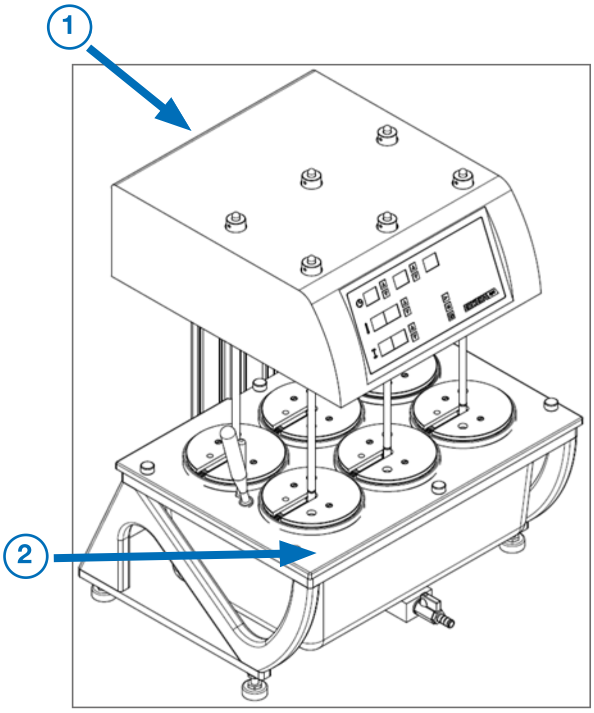
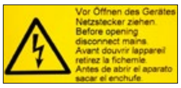


Abb. 1 Positions of the notes on the DT light

Position	Label	Description	Label location
1	 Vor Öffnen des Gerätes Netzstecker ziehen. Before opening disconnect mains. Avant douvrir lappareil retirez la fichemle. Antes de abrir el aparato sacar el enchufe.	Symbol: Hazard of electric shock! Notes: Before opening disconnect mains	Rear side of the dissolution tester and heater, clearly visible near the power supply connection
2		Symbol: Rotating element	Water bath cover at the margin in High Head devices

3 – Overview

3.1 – Description

The ERWEKA dissolution testers of DT light series have been designed according to the USP, BP, EP and DAB for performing dissolution tests of tablets, dragees, oblongs and other dosage forms.

Dissolution tests serve for determination of active substance release of solid dosage forms. At that active substance release means amount and speed with which the tested dosage form releases the active substance into the surrounding medium. The standardized conditions for these tests are described in pharmacopoeias.

The devices of DT light series represent an economic solution of dissolution testers as High Head models without automatic sampling system on basis of the ERWEKA DT 72x series. They are equipped with 6 (DT 126), 8 (DT 128) and 12 (DT 1212) test stations arranged in two rows respectively.

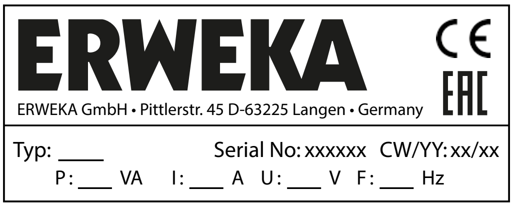
The device operation happens through touch-sensitive foil keys and various displays in the device‘s head.

The heater of DH 1520 type guarantees the constant and vibration-free distribution of the tempered water. An external temperature measurement sensor (PT 100) serves for checking the water bath temperature.

The printout of the test protocols is optionally possible with compatible printers.

3.2 – Type label

The type label is placed on the rear panel of the device and contains following data:



ERWEKA
ERWEKA GmbH • Pittlerstr. 45 D-63225 Langen • Germany
Typ: ____ Serial No: xxxxxx CW/YY: xx/xx
P: ___ VA I: ___ A U: ___ V F: ___ Hz

Typ: Device type
Serial No: Serial number
CW/YY: Calendar week/year of manufacture
P: Rated output in volts-amperes [VA] or in watts [W] *
I: Current in amperes [A] *
U: Voltage in volts [V]
F: Frequency in hertz [Hz]

* This data is optional, depending on the device.

3.3 – Device types

	DT 126 light	DT 128 light	DT 1212 light
Number of test stations	6	8	12

3.4 – Overview diagrams

DT 126 light

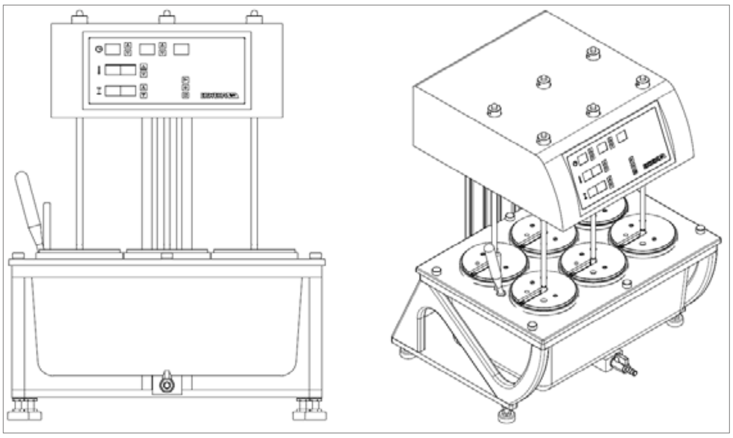
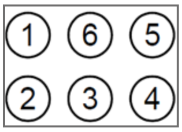


Fig. 2 DT 126 light - 6 test stations in two rows



①	⑥	⑤
②	③	④

Fig. 3 Numbering of test stations in DT 126 light

DT 128 light

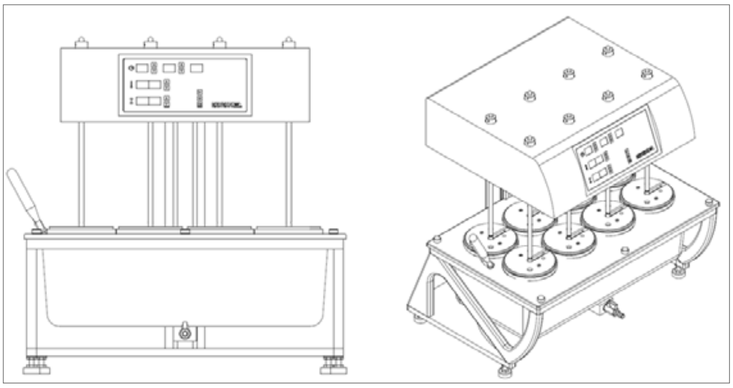
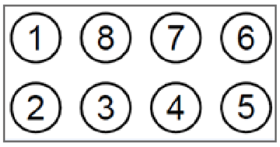


Fig. 4 DT 128 light - 8 test stations in two rows



①	⑧	⑦	⑥
②	③	④	⑤

Fig. 5 Numbering of test stations in DT 128 light

DT 1212 light

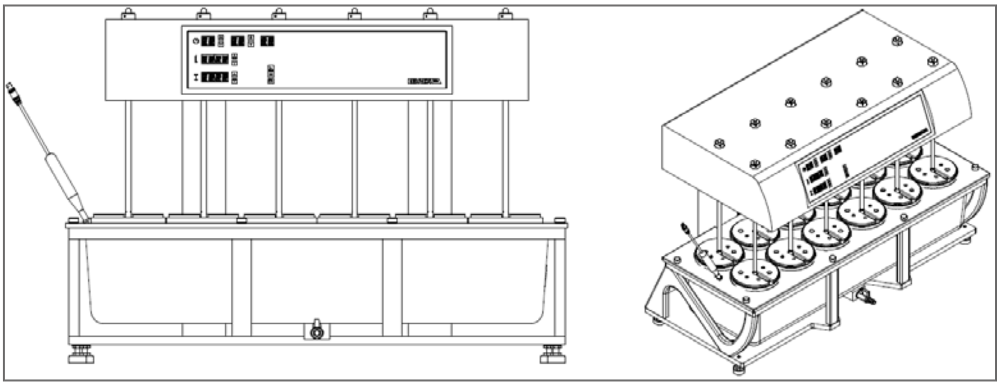
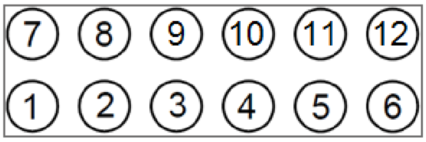


Fig. 6 DT 1212 light - 12 test stations in two rows



⑦	⑧	⑨	⑩	⑪	⑫
①	②	③	④	⑤	⑥

Fig. 7 Numbering of test stations in DT 1212 light

3.5 – Construction

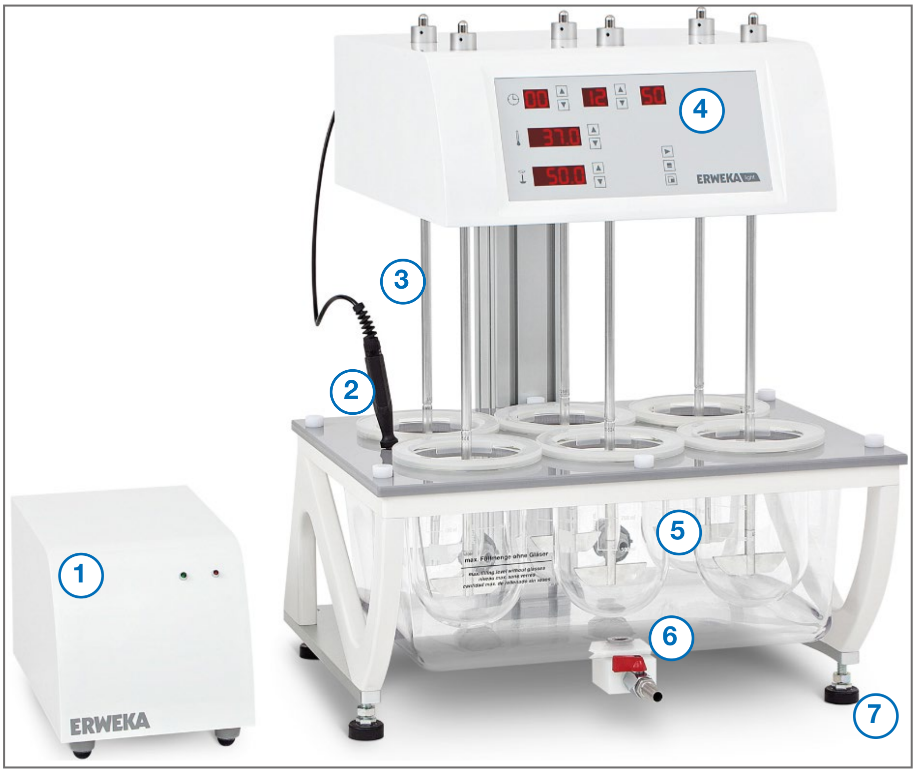


Fig. 8 DT 126 light with DH 1520 heater and external temperature sensor

[1]	Heater (DH 1520)
[2]	External temperature sensor (PT 100)
[3]	Stirring shaft with stirring element (here paddles for 6 test stations, in DT 128 light for 8 test stations and in DT 1212 for 12 test stations)
[4]	Operation area with displays and foil keys
[5]	Vessel (here for 6 test stations, in DT 128 light for 8 test stations and in DT 1212 for 12 test stations)
[6]	Water bath with outlet valve
[7]	Adjustable foot

3.6 – Operation elements and connections

3.6.1 – Connections and main switch

The main switch, power and other connections as well as the device fuses are located on the rear panel of the dissolution tester head.

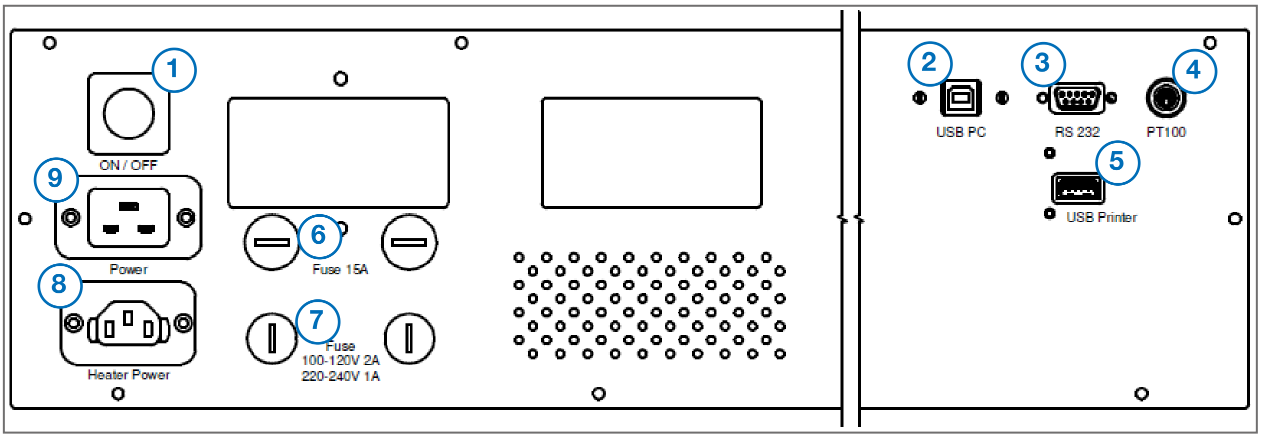


Fig. 9 Dissolution tester rear panel

[1] Main switch of dissolution tester
[2] USB B interface for firmware update
[3] RS 232 interface for heating
[4] Connection for temperature sensor (PT 100)
[5] USB A (e.g. for optional printer)
[6] Fuse 15 A
[7] Fuse 3.15 A
[8] Mains input for heater
[9] Mains input

The connections of the heater are located on the device rear panel.

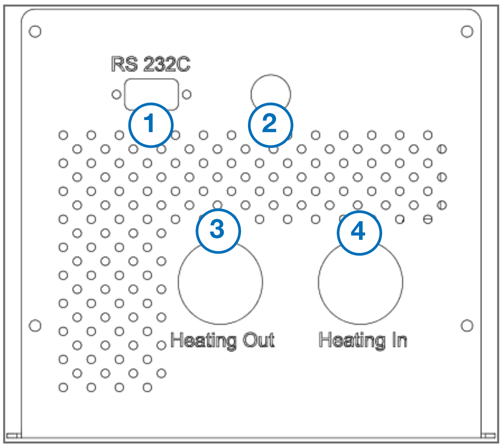
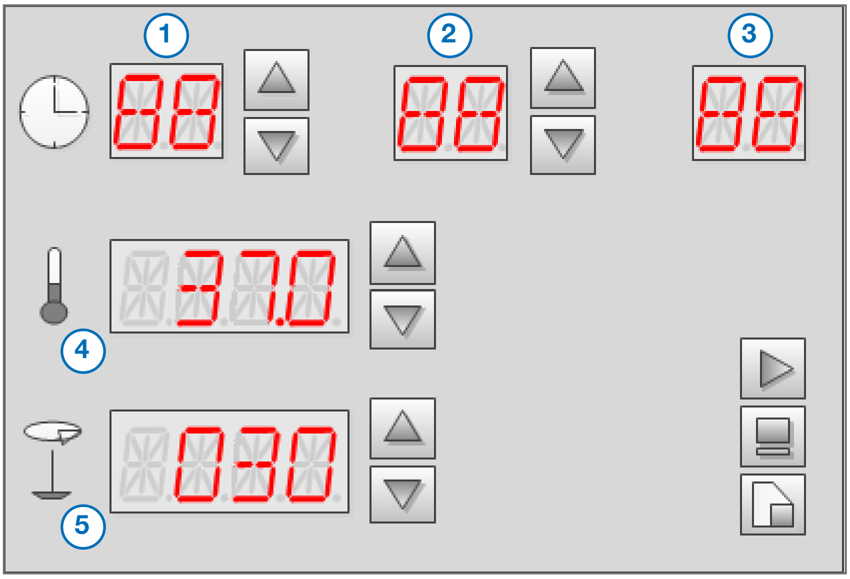


Fig. 10 Heater rear panel

[1] RS 232 interface
[2] Mains input
[3] Output for heated water
[4] Input for heated water

3.6.2 – Control panel

The control panel is located on the front panel of the dissolution tester head.



[1]	Upper display (time - hours)
[2]	Upper display (time - minutes)
[3]	Upper display (time - seconds)
[4]	Middle display (temperature)
[5]	Lower display (speed)

Fig. 11 Control panel of the dissolution tester

Key	Title	Function
△ ▽	Arrow keys	To scroll through menus or submenus, to select values
▷	The Start key	To start a test, to open a selected menu
□	The Stop key	To pause or stop a test, to exit the current menu
🗋	The Menu key	To open the user menu (TEST/CONF)

Acoustic signals

Any keypad input is confirmed by a beep. This beeping sound can be deactivated. See *5.2.4 – The SND menu item*.

Deactivating the beeping sound will also deactivate the alarm signal for test end. See *5.2.3 – The ALRM menu item*.

3.7 – Workplace

The dissolution tester is designed as a table-top device. It is operated from the front panel of the dissolution tester head. Connections and main switch are located on the rear panel of the dissolution tester head. Water bath, cover, stirring elements and vessels can be dismantled, e.g. for cleaning purposes.

3.8 – Technical data

	DT 126 light	DT 128 light	DT 1212 light
Dimensions			
Height [mm]	660	680	656
Width [mm]	510	642	932
Depth [mm]	450	482	444
Weight			
[kg]	30	38	60
Power supply			
	110/220/240 VAC; 50-60 Hz		
Safety fuses			
	15 A/3.15 A		
Safety			
Protection class	I/EN 61140		
Protection type	IP 21/IEC 529		
Test stations			
	6 in 2 rows	8 in 2 rows	12 in 2 rows
Speed			
	20 - 250 rpm		
Vessel			
Volume [ml]	Max. 1000 ml		
Temperature sensor in each vessel	—		
Temperature control			
	Optional with external temperature sensor PT 100		
Heating DH 1520			
Power consumption [W]	1500		
Temperature [°C]	15 - 50 (± 0.2)		
Interface	RS 232		
Water bath			
Volume [l]	14	20	20.7
Material	PET (one piece)		
Operation			
	Control panel with LED displays and keys		
Interfaces			
	RS 232, USB A (printer), USB B (firmware update), PT 100 connection		
Housing material			
	Laquered metal		
Environmental conditions			
Ambient temperature in operation	+10 °C up to +30 °C		
Storage and transport temperature	+5 °C up to +40 °C		
Relative humidity	25-80 % no condensation		
Airborne acoustic noise			
The A-weighted emission sound pressure level in the workplace is less than or equal to 70 dB(A), provided no influence from other devices or similar in the surrounding environment.			

4 – Installation

4.1 – Storage and transport conditions

The device should not be exposed to punches and vibrations.

Temperature and humidity should not exceed or fall below the values defined by ERWEKA. (See *3.8 – Technical data*.)

4.2 – Unpacking and checking

After receipt of the delivery, check the packaging and the device for transport damage.

On some packages you can see indicator labels, which change their colors in case of improper transporting. Check these labels for discoloration.

If undue transporting or any damage is evident, take a photo of this and send it to our ERWEKA service immediately. (See *1.2 – Service*.)

4.3 – Installation

4.3.1 – Positioning

Position the device on a horizontal, plane, stable surface, e.g. on a laboratory table, and pay attention so that not to displace it during the operation.

Use the adjustable feet to set the appropriate height and a horizontal plane position of the device. Check the horizontal adjustment with a bubble level.

For operation and access, when positioning the device, pay attention to the sufficient distance to the walls, cabinets or other fixed components of the facility.

Keep the device away from the following influences:

- Heat (heating, insolation)
- Direct draught through open windows, doors or air conditioning and ventilating systems
- Shaking
- Dampness

The on-site currently valid directives/standards for room air in the laboratory must be observed.

Do not position any objects onto the device.

4.3.2 – Acclimatization

If a cold device is moved to a warm environment, condensation may occur. Therefore you should allow the device to acclimatize for approximately two hours at room temperature, leaving it unplugged.

4.3.3 – Required setup environment

Ambient temperature during operation: +10 °C to +30 °C
Relative humidity: 25%-80% no condensation

4.4 – Preparation for operation

Antifreeze liquid present

When delivered, the device contains antifreeze liquid with Tyfocor® L (mixing ratio Tyfocor® L : water = 1 : 4) in the heating circuit. If required by the operator, the antifreeze liquid must be removed from the unit.

CAUTION
Risk of injury from contact with Tyfocor® L!
Wear protective gloves and safety glasses when handling Tyfocor® L.
If Tyfocor® L comes into contact with skin: wash with water and soap.
If Tyfocor® L comes into contact with the eyes: thoroughly rinse eyes under running water with eyelids held open and seek medical advice.
The product safety data sheet Tyfocor® L contains further information.

Spilt or leaked antifreeze liquid should be absorbed and discarded according to regulations. The product safety data sheet Tyfocor® L contains further information.

Note that product residues must be properly disposed of in accordance with the applicable environmental legislation.

If you add algicide

CAUTION
Risk of injury from contact with algicide!
Be careful when handling algicide. Wear protective gloves and safety glasses when handling algicide.
Read the relevant Algicide Safety Data Sheet and follow the safety instructions.

Spilt or leaked algicide should be absorbed with a liquid-binding material and discarded according to regulations. The relevant Algicide Safety Data Sheet contains further information.

1. Ensure that the heater and the water bath are located at the same level, the device is switched off and disconnected from the mains.

2. Assemble the tube connections between the water bath and the heater. For this use the delivered cables with quick coupling. Let off a tube end for filling.

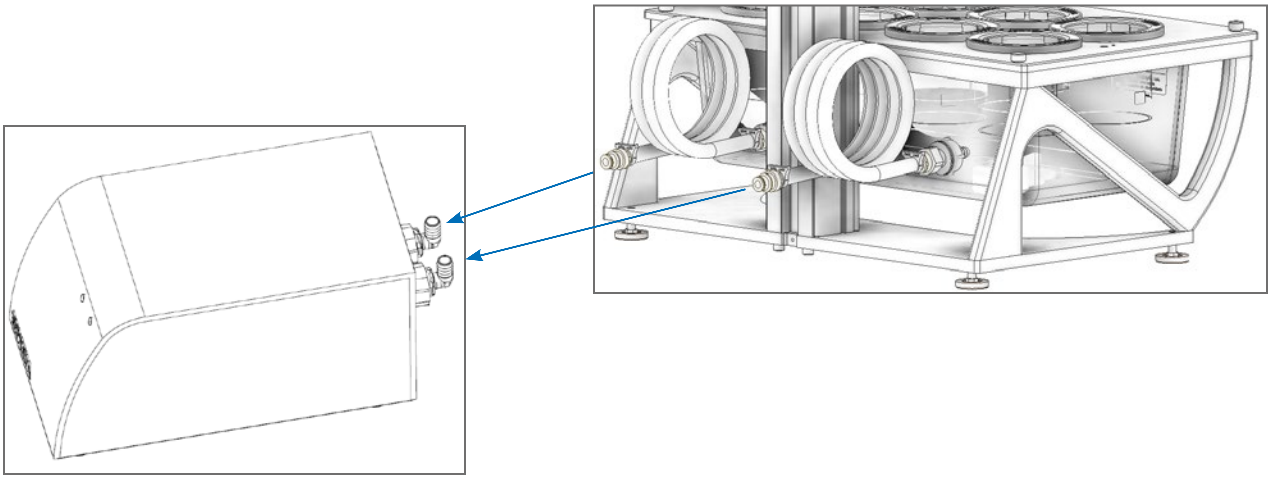
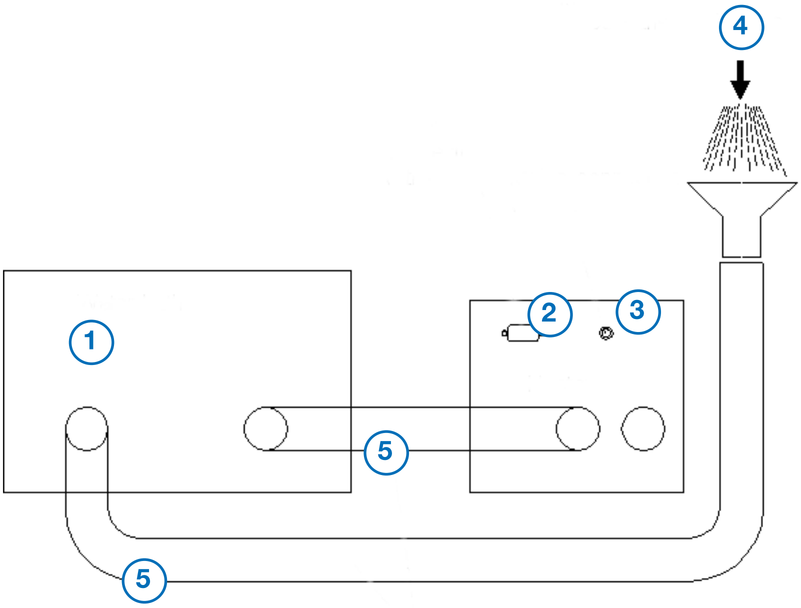


Fig. 12 Connection of the water bath of dissolution tester with the heater

Pay attention to that the tubes with quick coupling are latched correctly. It can be heard with „click“ sound.

3. Fill the water bath e.g. with demineralized water and, if demanded by the operator, with addition of algicide up to the mark. Ensure that the connection tubes to the heater are filled with water because the pump is not self-priming.



[1]	Water bath
[2]	Heater, serial connection with DT
[3]	Heater, mains connection with DT
[4]	Filling through hopper and tube
[5]	Tube with quick coupling

Fig. 13 Connection scheme

NOTICE

Do not bend, kink or clamp the tubes. Ensure that:

- There is no air in the system.
- The tubes are freely movable also during operation.
- The tubes are not damaged.

Read the directions for use of the product and the corresponding safety data sheet for handling and dosing of algicide. Pay attention to the safety precautions listed there.

4. Connect the tube end through which the filling was performed.

5. Insert the vessels into the orifices of the water bath cover.

6. Push the stirring shafts through the guides on the device‘s upper side until the supports are locked and then mount the stirring elements (baskets or paddles).

7. Check the horizontal alignment of the dissolution tester with a spirit level or digital gauge. Check respectively in the middle on the outer length and width edges of the head and water bath cover. If needed, adjust the device with the adjustable feet.

NOTICE

The exact horizontal alignment of the device is the condition for the appropriate performance of a dissolution test. Do not place any objects on the device.

4.5 – Connecting and switching on the device

See also *3.6 – Operation elements and connections.*

1. Connect the cables between the dissolution tester and the heater.

2. Plug the temperature measurement sensor into the jack on device rear panel and insert it into the corresponding orifice of the water bath cover.

3. If available, connect the external printer to the printer interface (USB A, device rear panel).

HAZARD of electric shock!
Electric devices are to be plugged into safety sockets only.
The voltage of the existing current supply is to be compared to the indications on the type label.

NOTICE

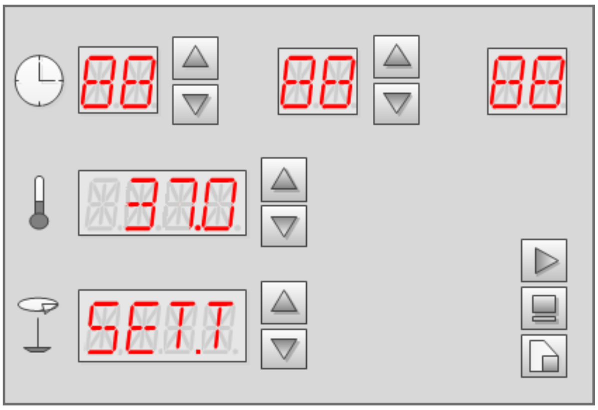
ERWEKA accepts no liability in case of wrong connection.

4. Plug the device into a safety socket. For this use the delivered network cable. To switch the device on, set the mains switch on the rear panel to I (ON).

   → As soon as the device is switched on, the pump of the heater starts to function. In case of air in the tubing it must be pressed out manually.

5. Check the water bath, heater and tubing for leakages.

   → The device is switched on now and following display is shown:



6. Using the arrow keys near the middle display set a start temperature.

7. Confirm it by pressing **Start**.

   → The water bath is warmed up to the set temperature. Then the water bath temperature is automatically maintained at the specified level.

or if you want to skip the initial warming

7. Press **Start** without setting a temperature value to specify the test parameters instead.

We recommend configuring the device according to your needs before specifying the test parameters and performing the tests.

To switch the device off, set the mains switch to 0 (OFF).

i More information about configuration and performing tests you will find in the following chapters of this instruction manual.

5 – Settings

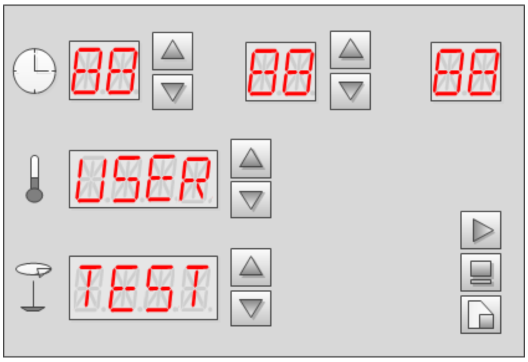
The settings are to be configured in two separate menus:

- Test settings in the TEST menu
- Device settings in the CONF menu

After pressing the **Menu** key you can select one of the menus on the lower display and enter the selected menu by pressing **Start**.

5.1 – The TEST menu

To enter the TEST menu:

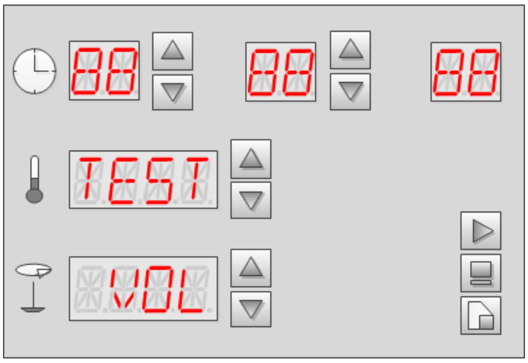


1. On the switched on device press the **Menu** key.
2. On the lower display select **TEST** with the arrow keys.
3. Confirm by pressing **Start**.

Menu item	Function	Chapter
VOL (Volume)	To select the vessel volume.	*5.1.1*
METH (Method)	To select the test method or kind of the stirring elements.	*5.1.2*
PRNT (Print)	To select the printing mode for protocols.	*5.1.3*
INFI (Prolonged test)	To select the parameters of prolonged test.	*5.1.4*
EXIT	To exit the TEST menu.	

Read the information on each menu item below.

5.1.1 – The VOL menu item



Use the arrow keys near the lower display to select the **VOL** item from the TEST menu and press **Start**.

Use the arrow keys near the lower display to select the required vessel volume and confirm it by pressing **Start**.

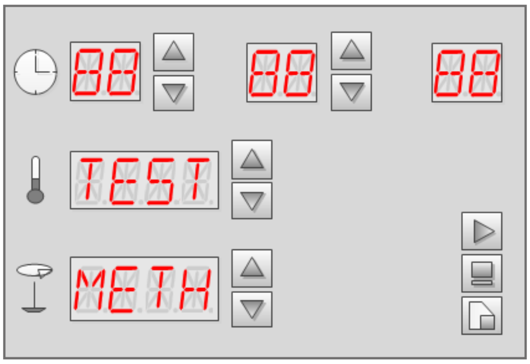
You can select 1000, 900, 750 or 500 ml because the devices of the DT light series have 1000 ml vessels.

For other values you can additionally select ML. In this case, the report contains an empty area where you can enter the individual volume manually.

By pressing **Stop** you can leave the VOL menu item without changes.

5.1.2 – The METH menu item

Use the arrow keys near the lower display to select the **METH** item from the TEST menu and press **Start**.



Use the arrow keys near the lower display to select the required test method and confirm it by pressing **Start**.

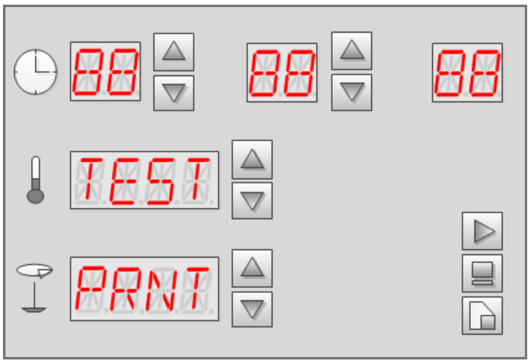
Methods available:

- BSKT — Basket
- PADL — Paddle
- POVD — Paddle over Disk
- CYLN — Rotating Cylinder
- BLNK — For other methods. In this case, the report contains an empty area where you can enter the individual method manually.

By pressing **Stop** you can leave the METH menu item without changes.

5.1.3 – The PRNT menu item

Use the arrow keys near the lower display to select the **PRNT** item from the TEST menu and press **Start**.



Use the arrow keys near the lower display to select the required printing mode and confirm it by pressing **Start**.

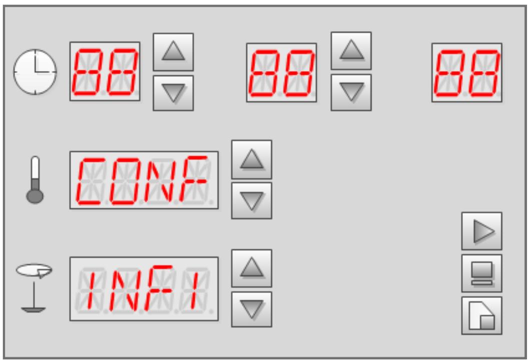
Printing modes available:

- AUTO — to print the protocol automatically after test end
- ASK — to print the protocol after confirmation
- OFF — not to print the protocol

By pressing **Stop** you can leave the PRNT menu item without changes.

5.1.4 – The INFI menu item

Use the arrow keys near the lower display to select the **INFI** item from the TEST menu and press **Start**.



Use the arrow keys near the lower display to select the parameters of prolonged test and confirm it by pressing **Start**.

Parameters:

- RUN — to activate/deactivate the prolonged test (ASK = activate, OFF = deactivate)
- TIME — to set the runtime of prolonged test (1-59 minutes)
- RPM — to set the speed of prolonged test (20-250 rpm)

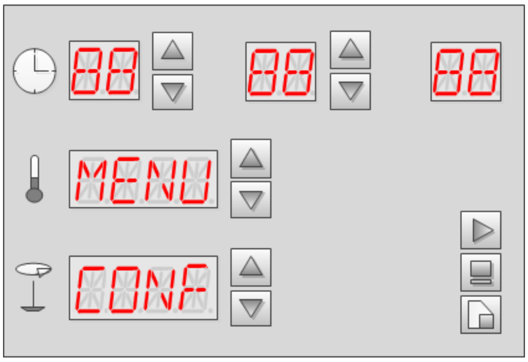
After the confirmation the test will be continued with the preset runtime and speed. The prolonged test can be aborted by pressing Stop. Pause is impossible for prolonged tests.

By pressing **Stop** you can leave the INFI menu item without changes.

CAUTION
Danger of being entangled and drawn! Rotating shafts with stirring elements. Tie long hair back. Wear tightly fitting clothes. Do not wear any neckties, scarfs etc. that could become entangled onto the shafts.

5.2 – The CONF menu

To enter the CONF menu:



1. On the switched on device press the **Menu** key.
2. On the lower display select **CONF** with the arrow keys.
3. Confirm by pressing **Start**.

Menu item	Function	Chapter
HEAD (Head type)	This menu item is locked (in DT 12x series).	*5.2.1*
COUN (Time counting)	To set the time counting up or down.	*5.2.2*
ALRM (Alarm)	To set the alarm before the test end.	*5.2.3*
SND (Key sound)	To enable/disable the key sound.	*5.2.4*
LED (Display brightness)	To adjust the display brightness.	*5.2.5*
T.OFF (Temperature offset)	To set a temperature offset value.	*5.2.6*
AJ.PT (PT 100 adjustment)	To adjust the PT 100.	*5.2.7*
AJ.HE (Heater adjustment)	To adjust the heater.	*5.2.8*
CAL.T (Temperature sensor calibration)	To calibrate the temperature sensors (heater and PT 100).	*5.2.9*
DFLT (Default settings)	To restore the default (manufacturer‘s) settings.	*5.2.10*
USE (Usage)	To display the device usage hours.	*5.2.11*
REP (Protocol)	Settings for the protocols.	*5.2.12*
DATE (Time settings)	To specify the date and time.	*5.2.13*
PWMG (Password)	To set passwords.	*5.2.14*
PORT (Interface)	To set the port for device connections.	*5.2.15*
VER (Version)	Display of the firmware version.	*5.2.16*
EXIT	To exit the CONF menu.	

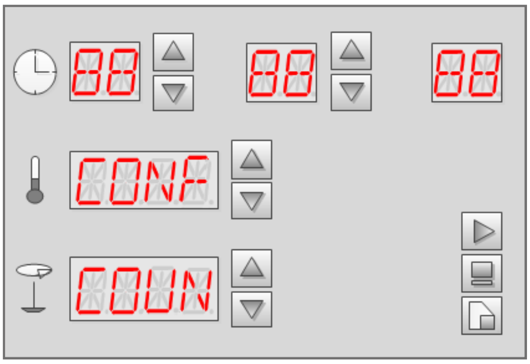
Read the information on each menu item below.

5.2.1 – The HEAD menu item

The HEAD menu item is locked for DT light because the devices of this series are High Head device types only.

5.2.2 – The COUN menu item

Use the arrow keys near the lower display to select the **COUN** item from the CONF menu and press **Start**.



Use the arrow keys near the lower display to select an option for the time counting and confirm it with **Start**.

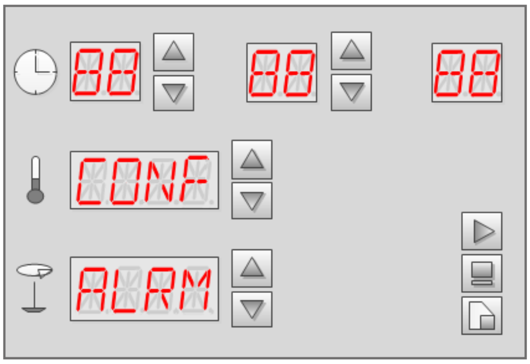
Options:

- UP — the time is counted up on the display
- DOWN — the time is counted down on the display

By pressing **Stop** you can leave the COUN menu item without changes.

5.2.3 – The ALRM menu item

Use the arrow keys near the lower display to select the **ALRM** item from the CONF menu and press **Start**.



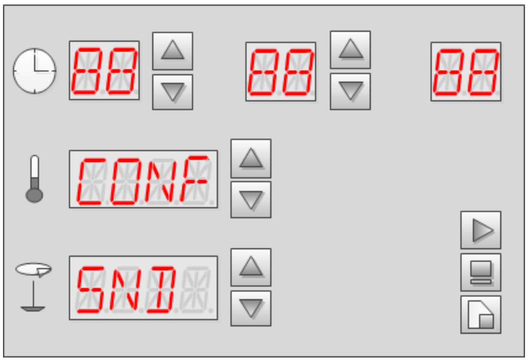
Enable the alarm before test end by selecting **ON** (**OFF** for disabling) using the arrow keys near the lower display. Confirm the setting by pressing **Start**.

By pressing **Stop** you can leave the ALRM menu item without changes.

For an active alarm the sound in the SND menu item must be also switched on.

5.2.4 – The SND menu item

Use the arrow keys near the lower display to select the **SND** item from the CONF menu and press **Start**.



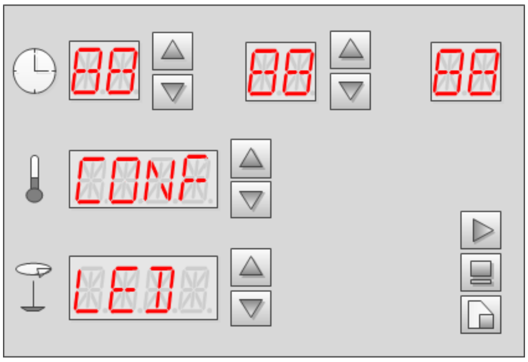
Enable the key sound by selecting **ON** (**OFF** for disabling) using the arrow keys near the lower display and confirm it by pressing **Start**.

By pressing **Stop** you can leave the SND menu item without changes.

ERWEKA recommends an enabled key sound because it confirms not only data inputs but also serves as hints and alarm.

5.2.5 – The LED menu item

Use the arrow keys near the lower display to select the **LED** item from the CONF menu and press **Start**.

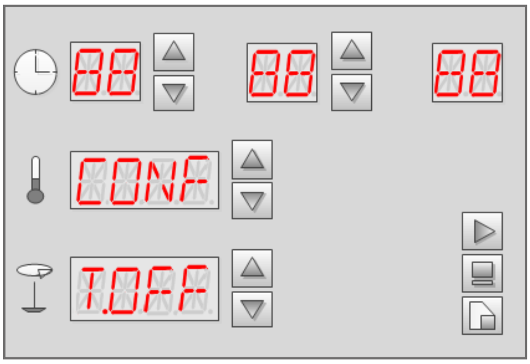


Use the arrow keys near the lower display to select the required brightness (0 - 9) and confirm it by pressing **Start**.

By pressing **Stop** you can leave the LED menu item without changes.

5.2.6 – The T.OFF menu item

Use the arrow keys near the lower display to select the **T.OFF** item from the CONF menu and press **Start**.



Use the arrow keys near the lower display to select the required temperature offset value (from -2,5 °C to + 2,5 °C) and confirm it by pressing **Start**.

By pressing **Stop** you can leave the T.OFF menu item without changes.

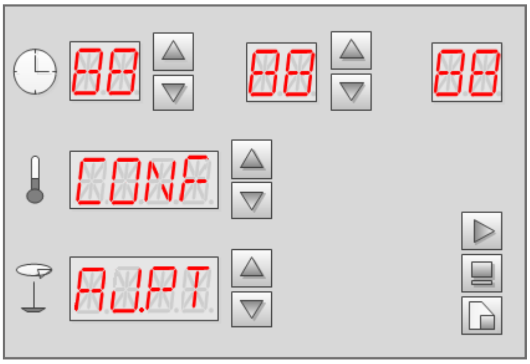
Offset (Temperature)
This value serves as a compensation of temperature losses during the heat transfer. It is added to the nominal value.
Example: When the thermostat is set to a nominal value of 37 °C and the temperature offset – to 0.5 °C, the thermostat will heat the medium up to 37.5 °C. In this way the constant temperature value of 37 °C is ensured in all containers.

5.2.7 – The AJ.PT menu item

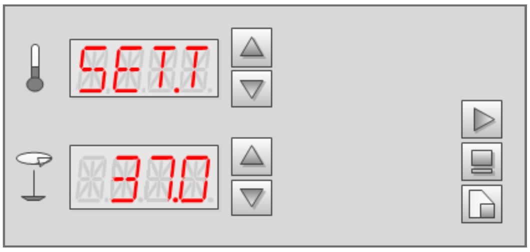
This menu item is available only when PT 100 is connected!

NOTICE The temperature measurement sensor PT 100 is adjusted with the help of an external reference thermometer. Always use a checked calibrated thermometer as reference thermometer.

Use the arrow keys near the lower display to select the **AJ.PT** item from the CONF menu and press **Start**.

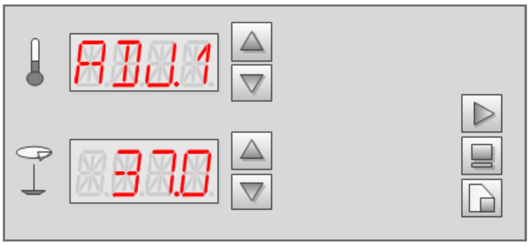


1. Set the first temperature value with which you want to adjust the PT 100. For this use the arrow keys near the lower display.



2. Confirm with **Start**.

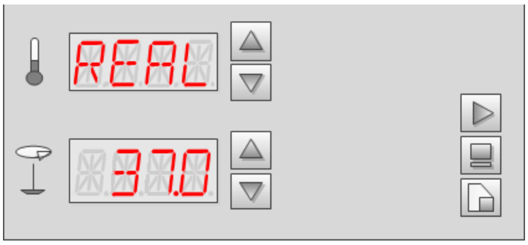
   → The following information is shown.



3. Wait until the water bath is warmed to the set temperature.

   → The lower display shows the temperature measured currently by PT 100.

4. As soon as the shown temperature is stable, press **Start** for adjustment.

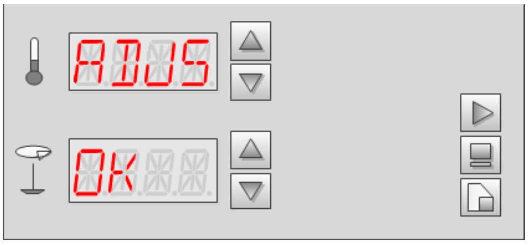


5. Measure the water bath temperature with the reference thermometer.

6. Compare both temperature values (device and reference thermometer). If the values deviate from each other, specify the value shown by the reference thermometer using the arrow keys near the lower display.

7. Press **Start**.

   → The display can look as follows.



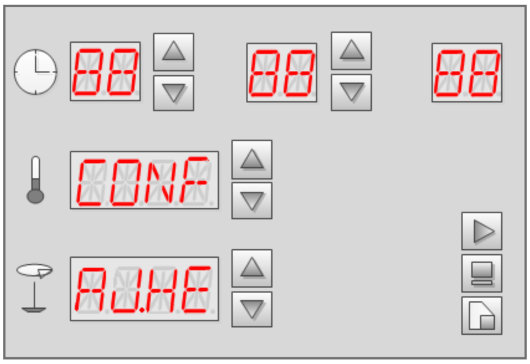
- OK — PT 100 was successfully adjusted.
- Err — communication with the PT 100 is lost; repeat adjustment.

Depending on the enabled printing mode, a protocol printout is possible after the adjustment. (See *5.1.3 – The PRNT menu item*.) Ensure that the printer is connected and switched on.

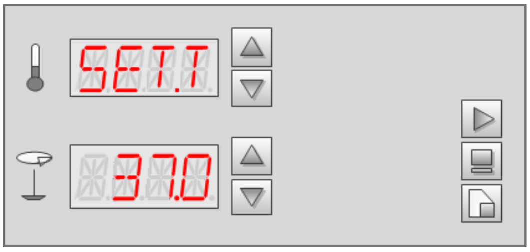
5.2.8 – The AJ.HE menu item

> **NOTICE** The heater is adjusted with the help of an external reference thermometer. Always use a checked calibrated thermometer as reference thermometer.

Use the arrow keys near the lower display to select the **AJ.HE** item from the CONF menu and press **Start**.

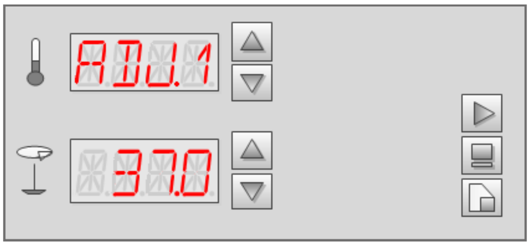


1. Set the first temperature value with which you want to adjust the heater. For this use the arrow keys near the lower display.



2. Confirm with **Start**.

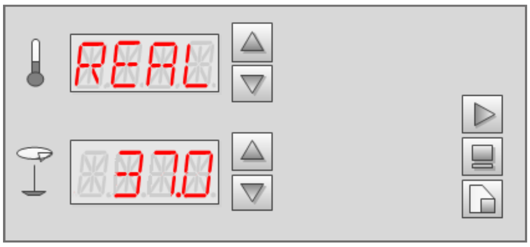
   → The following information is shown.



3. Wait until the water bath is warmed to the set temperature.

   → The lower display shows the currently measured temperature of the heater.

4. As soon as the shown temperature is stable, press **Start** for adjustment.

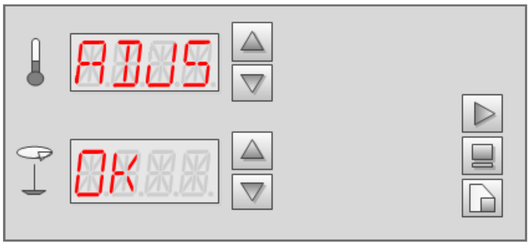


5. Measure the water bath temperature with the reference thermometer.

6. Compare both temperature values (device and reference thermometer). If the values deviate from each other, specify the value shown by the reference thermometer using the arrow keys near the lower display.

7. Press **Start**.

   → The display can look as follows.



- OK — heater was successfully adjusted.
- Err — communication with the heater is lost; repeat adjustment.

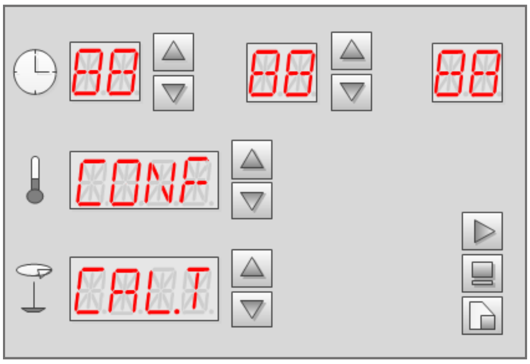
> Depending on the enabled printing mode, a protocol printout is possible after the adjustment. (See *5.1.3 – The PRNT menu item*.) Ensure that the printer is connected and switched on.

5.2.9 – The CAL.T menu item

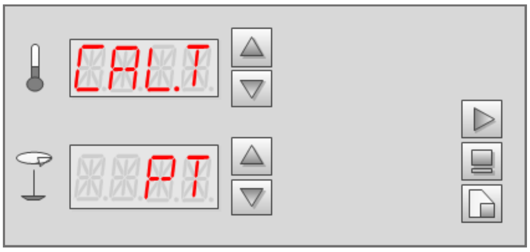
NOTICE

The temperature sensors (heater and PT 100) are calibrated with the help of an external reference thermometer. Always use a checked calibrated thermometer as reference thermometer.

Use the arrow keys near the lower display to select the **CAL.T** item from the CONF menu and press **Start**.

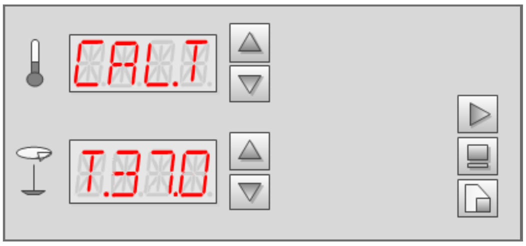


1. Select the temperature sensor which you want to calibrate (heater or PT 100). For this use the arrow keys near the lower display.



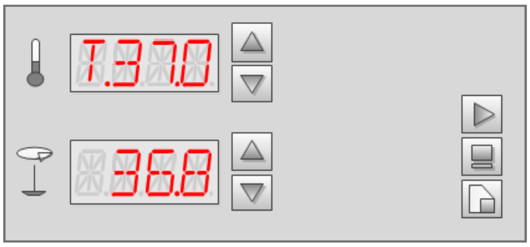
2. Confirm with **Start**.

   → The preset calibrated value of the selected temperature sensor is shown blinking on the lower display.



If the temperature is not shown, then the sensor (heater or PT 100) is not connected.

3. Specify the target temperature value using the arrow keys near the lower display.

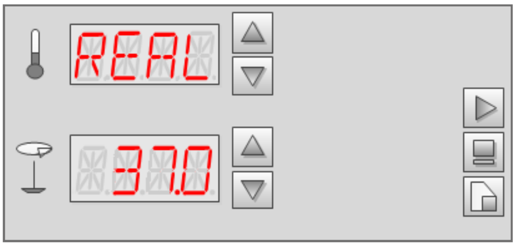


4. Press **Start**.

5. Measure the water bath temperature with the reference thermometer.

6. When the target temperature (±0,2 °C) is reached, press **Start** again.

   → The value is shown blinking on the lower display.



7. Compare both temperature values (device and reference thermometer). If the values deviate from each other, specify the value shown by the reference thermometer using the arrow keys near the lower display.

8. Confirm with **Start**.

NOTICE

If the calibration has failed, it is recommended to perform a new adjustment and repeat the calibration. (See *5.2.7 – The AJ.PT menu item* and *5.2.8 – The AJ.HE menu item*.)

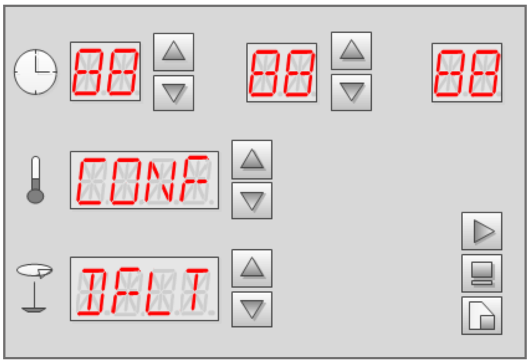
NOTICE

If the target temperature is not reached, it is recommended to adjust the temperature offset. (See *5.2.6 – The T.OFF menu item*.)

Depending on the enabled printing mode a protocol printout is possible after the calibration. (See *5.1.3 – The PRNT menu item*.) Ensure that the printer is connected and switched on.

5.2.10 – The DFLT menu item

Use the arrow keys near the lower display to select the **DFLT** item from the CONF menu and press **Start**.



To restore the default settings, press **Start**.

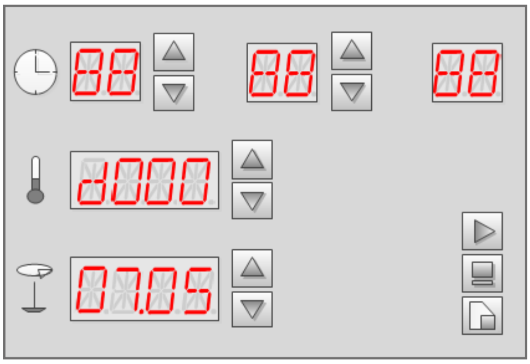
By pressing **Stop** you can leave the DFLT menu item without changes.

> **i** Default settings are device settings from the manufacturer.

> **i** If you have configured a password for the Pwmg menu, it won't be reset.

5.2.11 – The USE menu item

Use the arrow keys near the lower display to select the **USE** item from the CONF menu and press **Start**.



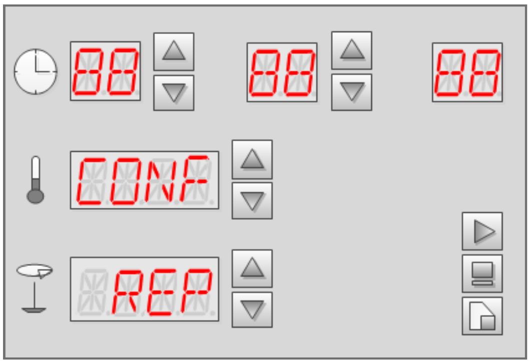
Display:

- middle display — operation time in days (d can be set up to 999 days)
- lower display — operation time in hours and minutes (in the example 7 hours and 5 minutes)

By pressing **Stop** leave the USE menu item.

5.2.12 – The REP menu item

Use the arrow keys near the lower display to select the **REP** item from the CONF menu and press **Start**.



Use the arrow keys near the lower display to select the required option of the protocol settings and confirm it by pressing **Start**.

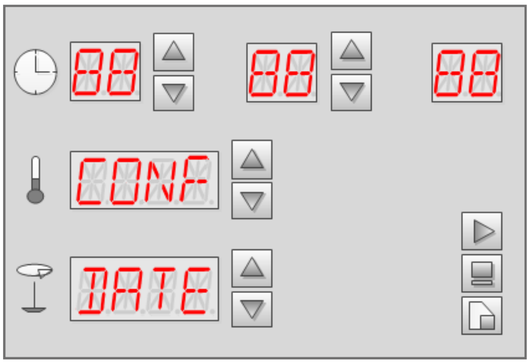
Options:

- LAST — to print the last protocol again
- LANG — to select the protocol language (English, German)
- P.TYP — to select the printer type (PCL conventional for A4 paper format or USB thermal printer for small printouts)

By pressing **Stop** you can leave the REP menu item without changes.

5.2.13 – The DATE menu item

Use the arrow keys near the lower display to select the **DATE** item from the CONF menu and press **Start**.



Use the arrow keys near the lower display to select the function to be set and confirm it by pressing **Start**.

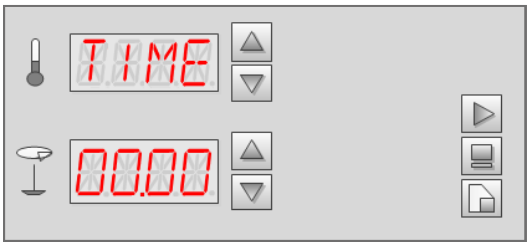
Adjustable functions:

- TIME — time
- DAY — day
- YEAR — year
- FRMT— display format

Password protection

The Date menu item can be protected with a four-digit password presented with asterisks. To enter the password, use the Down/Up arrow keys (the lower ones for the entry of digits and the middle ones for the position change). The password is set in the Pwmg menu item. (See *5.2.14 – The PWMG menu item*.)

when you have selected TIME:

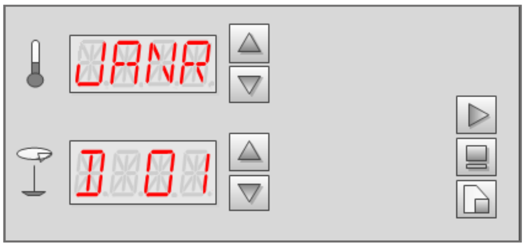


» set the hours in the middle display by pressing or holding the accompanying arrow keys.
» set the minutes in the lower display by pressing or holding the accompanying arrow keys.

To save the time setting, press **Start**.

→ The DATE menu is shown again.

when you have selected DAY:

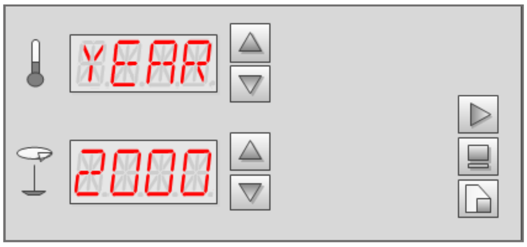


» set the month in the middle display by pressing the accompanying arrow keys.
» set the day in the lower display by pressing the accompanying arrow keys.

To save the day setting, press **Start**.

→ The DATE menu is shown again.

when you have selected YEAR:

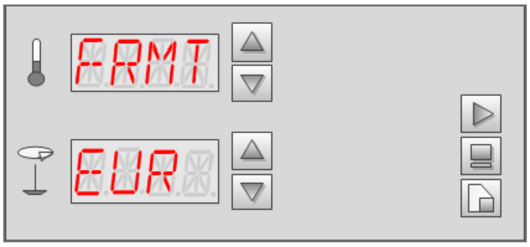


» set the year in the lower display by pressing the accompanying arrow keys.

To save the year setting, press **Start**.

→ The DATE menu is shown again.

when you have selected FRMT:



» set the format in the lower display by pressing the accompanying arrow keys.

- EUR — European date format (day/month/year)
- USA — American date format (month/day/year)

To save the format setting for the date display, press **Start**.

→ The DATE menu is shown again.

5.2.14 – The PWMG menu item

Protect the Date (time setting) and Pwmg (password management) menus each with a password. Your passwords must consist of a four-digit sequence, which you specify in the Pwmg menu item.

> If you wish no protection for the Date and Pwmg menus, enter “9999” each time as a default password.

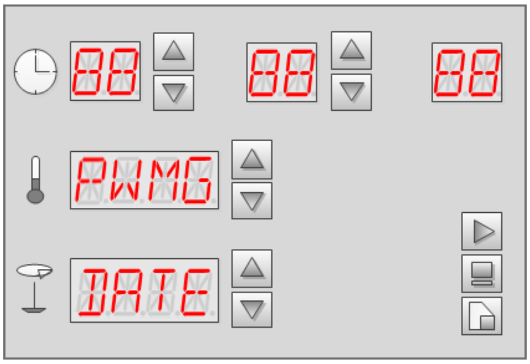
> If you have forgotten the password, contact ERWEKA Service under *support@erweka.com* to reset the passwort.

Password protection

The Pwmg menu item can be protected with a four-digit password represented with asterisks, see above. To enter the password, use the Down/Up arrow keys (the lower ones for the entry of digits and the middle ones for the position change).

To open the Pwmg menu:

Use the arrow keys near the lower display to select the **PWMG** item from the CONF menu and press **Start**.



You can set passwords for 2 menu items:

- PWST — password for the Pwmg menu
- DATE — password for the Date menu

To set the passwords:

1. In the Pwmg menu, use the lower arrow keys to select the password you want to set (Pwst/Date).
2. To confirm the selection, press **Start**.

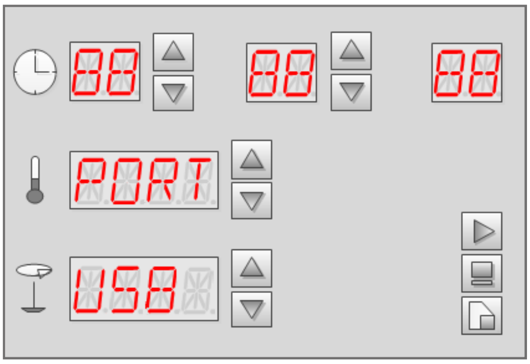
   → In the middle display, Pwst or Date are shown.

   → In the lower display, 4 asterisks are shown for the password input.
3. Define the new password then:
   - Use the middle arrow keys to switch the position.
   - Use the lower arrow keys to select a digit for the position blinking in the lower display.
   - Step through all 4 positions.
4. To confirm the new password, press **Start**.

   → The password will be saved.

5.2.15 – The PORT menu item

Use the arrow keys near the lower display to select the **PORT** item from the CONF menu and press **Start**.



Use the arrow keys near the lower display to select a port type and confirm it by pressing **Start**.

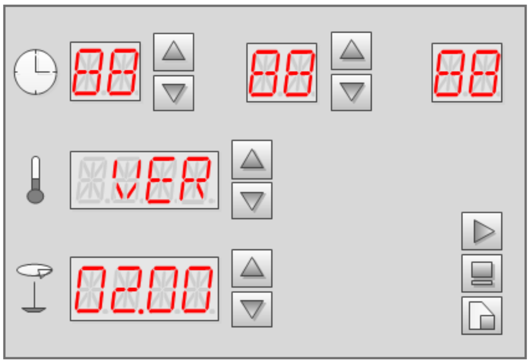
Port types:

- USB — connections without PC (heater is connected directly with dissolution tester; standard)
- COM — connections through PC (heater and dissolution tester connected with the PC respectively)

By pressing **Stop** you can leave the PORT menu item without changes.

5.2.16 – The VER menu item

Use the arrow keys near the lower display to select the **VER** item from the CONF menu and press **Start**.



The firmware version installed on the device is shown on the lower display. (In the example it is firmware version 2.00).

To return to the CONF menu, press any key.

6 – Performing Tests

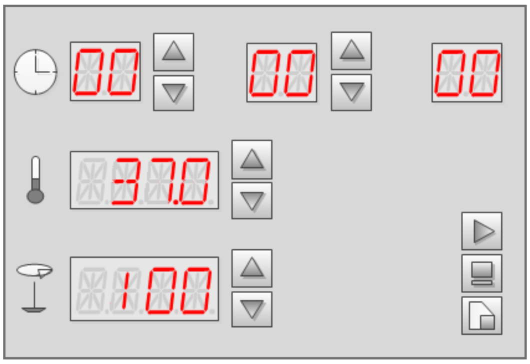
You can perform tests according to specified time, temperature and speed.

NOTICE Before performing tests ensure that the device is positioned, connected, calibrated appropriately and configured according to your specifications. (See previous chapters.)

6.1 – Performing a test

The device is switched on and ready for operation and the water bath has the target temperature. (See *4.5 – Connecting and switching on the device*.)

1. Press **Start**.



→ The device is in the main menu. The standard test parameters are shown:

- Time (three upper displays, from left to right: hours, minutes, seconds)
- Current water bath temperature (middle display)
- Stirring speed set previously (lower display)

Single pressing the arrow keys increases or decreases the value by one unit. Pressing and holding the arrow keys increases or decreases the value with continuous acceleration.

2. Use the arrow keys near the time display to enter the test time in hours and/or minutes.

The maximal test time that can be specified is 99 hours, 59 minutes and 00 seconds.

You can specify also 00 hours, 00 minutes and 00 seconds as test time. This means that the test time is unlimited and the test can be continued till the manual stop by the user.

3. Use the arrow keys near the temperature display to enter the temperature for the test.

The temperature that can be specified must be in the range from 15 °C to 50 °C!

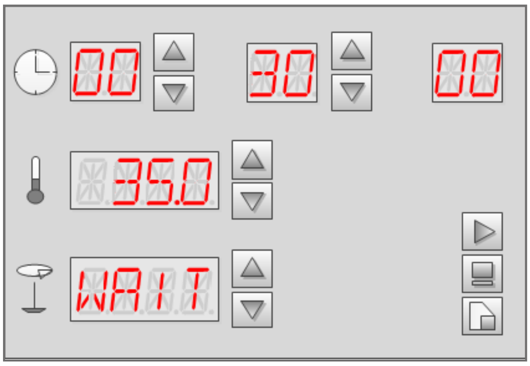
4. Use the arrow keys near the speed display to enter the stirring speed for the test [rpm or min^{-1}].

The speed that can be specified must be in the range from 20 min^{-1} to 250 min^{-1}!

5. After you have specified the test parameters, press **Start** to begin the test.

   → The device enters the waiting mode. The heater maintains the specified test temperature level in the water bath.

The test parameters (test time, temperature and speed) cannot be changed in the waiting mode.



If you press Stop in the waiting mode:

→ the main menu of the previous test is shown.

If you press Start in the waiting mode:

→ the test mode is changed.

In case you start a test before achieving the required test temperature, the current temperature value blinks on the middle display. This is also followed by an alarm signal, if the sound is enabled. (See *5.2.4 – The SND menu item*.)

NOTICE

ERWEKA recommends not to start a test before achieving the required water bath temperature (test temperature).

The temperature value shown on the middle display is the temperature from the heater. If the external PT 100 is connected, its temperature value is shown on the display.

6. To start the test, press **Start**.

7. Put the tablets into the vessels.

CAUTION
Danger of being entangled and drawn!
Rotating shafts with stirring elements. Tie long hair back. Wear tightly fitting clothes. Do not wear any neckties, scarfs etc. that could become entangled onto the shafts.

The rotation of stirring elements begins with lower speed. During 5 seconds the device accelerates to the specified test speed.

Depending on the time counting mode the test time is counted up or down. (See *5.2.2 – The COUN menu item*.)

Test end

Depending on the specified configuration settings the dissolution test is either finished in the end of the specified test time or is prolonged to the stop by the user. (See *5.1.4 – The INFI menu item*.)

Prolonged test

To prolong the dissolution test, set INFI to RUN and ASK. After the confirmation the test will be continued with the preset runtime and rotating speed. The prolonged test is aborted as soon as you press Stop.

Pause is impossible for prolonged tests. More information on test pauses you will find in the following subchapter.

Protocol

In the test end a protocol is generated and printed out according to the current printing setting. (See *5.2.12 – The REP menu item*.)

6.2 – Pausing/aborting a test

By pressing **Stop** you can pause a test manually.

- The stirring is stopped.
- The time counting is stopped.

The device is in the waiting mode.

Prolonged tests cannot be paused. They are finished as soon as you press Stop.

By pressing **Start** you can continue the paused test.

By pressing **Stop** again the paused test is finally aborted.

Due to enabled printing setting a protocol for the aborted test is printed out.

7 – Protocols (Optional)

After the test end a protocol is generated.

This protocol is stored in the device till the start of the next test. The protocols for finished tests are printed out automatically if:

- your device has a printer interface (optional)
- the printer is connected properly, switched on, not in standby mode and not shut down
- the printing mode is set to AUTO (see *5.1.3 – The PRNT menu item*)

You can also configure settings for protocol printout in the Configuration menu. (See *5.2.12 – The REP menu item*.)

> In case your device has no printer interface you can order it separately. For more information contact ERWEKA sales department.

ERWEKA supports the following printer models that can be connected to the devices of DT light series:

- HP LaserJet Pro M203dn
- HP LaserJet Pro 402 dne
- Brother HL-L2370DN
- Canon i-SENSYS LBP162dw
- Kyocera ECOSYS P2235dn
- OKI B432dn

8 – Maintenance

8.1 – Cleaning

Ensure that the device is cleaned regularly. The device is to be cleaned after each test and at least once a month. Spilt media must be removed immediately. Read the following instructions thoroughly before you begin with the cleaning.

The vessels and stirring elements must be cleaned after each test.

WARNING
Danger when handling media!
Wear personal protective gear and safety glasses when necessary. Observe safety regulations for work in laboratories.

HAZARD of electric shock when cleaning the electric devices!
Disconnect the mains supply for cleaning the electric devices. Switch the device off and unplug it for cleaning. Clean the electrical instruments without liquids.

NOTICE Damage to the device may be caused if the cleaning is not carried out or not as described here.

Note that product residues must be properly disposed of in accordance with the respective valid environmental legislation.

To clean the device

1. Disconnect the mains supply and all device connections.
2. Dismount the stirring elements and shafts.
3. Empty the vessels and water bath.

CAUTION
Residual test medium! Wear the appropriate protective gear.

4. Clean the stirring elements and shafts as described below *8.1.1 – Stirring elements/shafts cleaning*.
5. Unscrew the water bath cover and remove it.

6. Clean the water bath, cover, vessels. Clean the water bath using a special cleansing agent for acrylic glass and then rinse it with warm water.

NOTICE The water bath and water bath cover are made of PET plastic. Plastics are sensitive to abrasive (scratching) cleaning agents such as scouring cream or powder; these agents roughen and damage the surface. To clean, use water with some washing-up liquid, and for tougher stains use a special plastic cleaning agent.

Vessels without centering rings and stirring elements can be cleaned in a dish washer.

7. Clean the plate under the water bath.

8. Wipe the device with a soft and slightly damped cloth.

NOTICE Do not use a wet cloth but slightly damped one. Do not add any chemical cleansing agents to the cleaning water. For the lacquered housing parts use no cleansing agents which attack this material.

In case of heavy contamination, use a damp cloth and dab the cleaned areas dry.

8.1.1 – Stirring elements/shafts cleaning

NOTICE Stirring elements and shafts are made of stainless steel. Contact with various chemicals can lead to corrosion in long term. To avoid this, observe the cleaning instructions listed below.

1. Use germ-free water to clean.

ERWEKA recommends showering as a cleaning method.

2. Clean all stirrers and shafts after each use.

This also includes those which are not in direct use, but were mounted in the device.

3. Thoroughly clean stirring elements and shafts, over their whole area.

4. Dry the cleaned stirring elements and shafts immediately and completely.

ERWEKA recommends the use of a blow dryer or similar. This is important to avoid buildup during drying.

Never let cleaned stirring elements and shafts dry off, e.g. by depositing on paper. The residual drops of water may still contain substances that cause corrosion after drying.

8.2 – Inspection and maintenance

Ensure that the device is regularly inspected and each time is clean.

HAZARD of electric shock!
Before installation work on electrical devices, always switch off the device and disconnect it from the power supply.

To ensure a long lifetime of your devices and systems, we recommend a regular maintenance performed by our specialized staff.

8.3 – In longer standstills

- Switch the device off.
- Disconnect the device from the power supply.
- Disconnect all device connections.
- Dismount additional components.
- Empty and rinse all containers and hoses.
- Clean the device thoroughly.
- Store the device, its components and instruction manual. See the storage conditions defined by ERWEKA in *3.8 – Technical data*.

NOTICE Non-performance of the instructions given above can lead to damages.

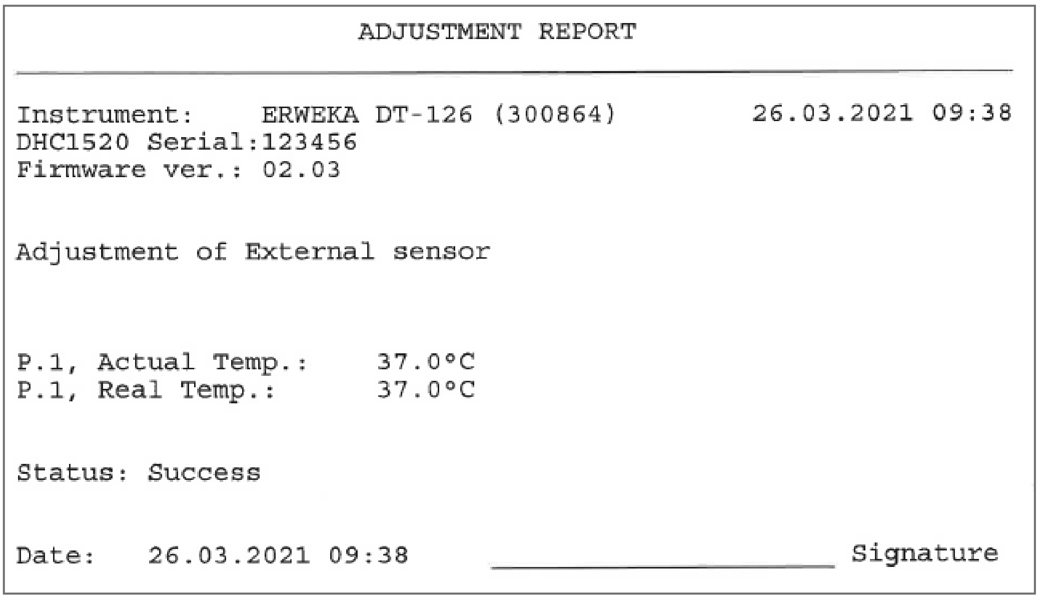
8.4 – Spare parts

NOTICE Electronic and mechanical replacements are to be made by the ERWEKA personnel or approved by ERWEKA.

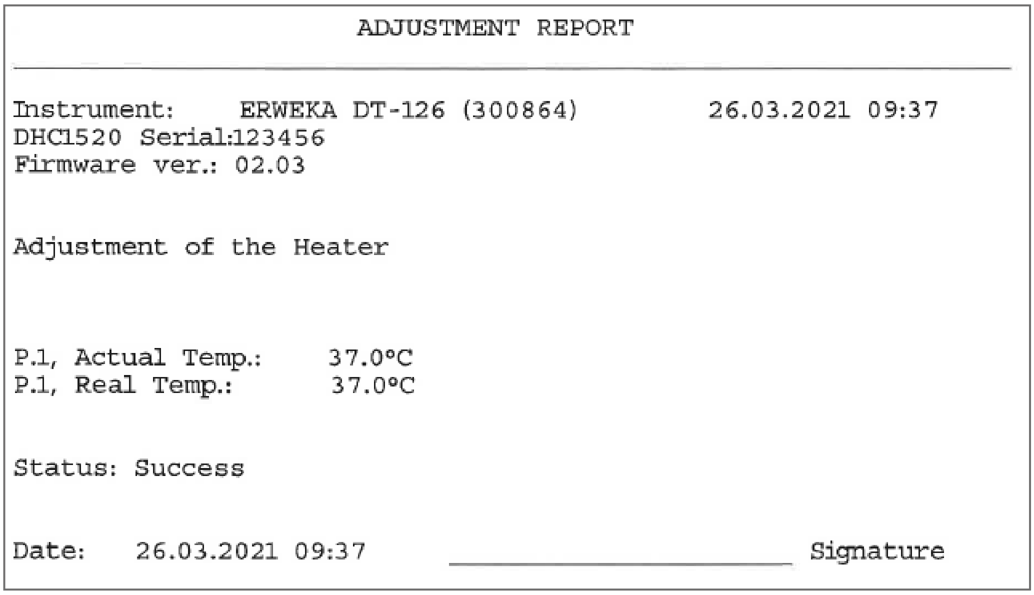
Only original spare parts or components released by ERWEKA should be used. Only repairs or changes on the device performed by the ERWEKA technicians or approved explicitly by ERWEKA are to be made.

Attachment

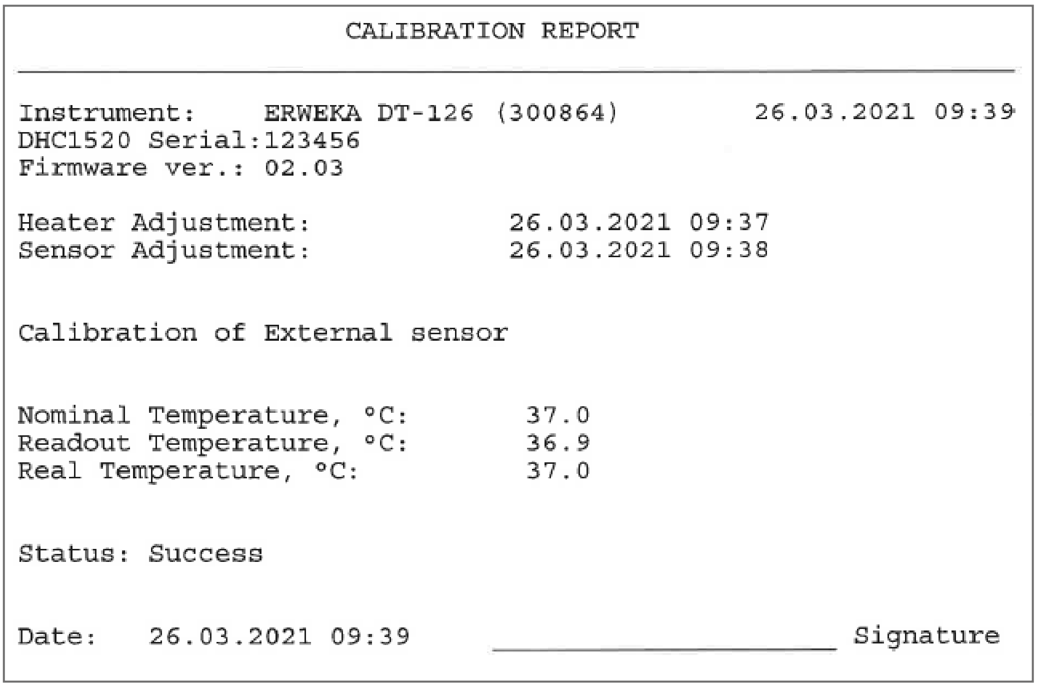
Example protocols



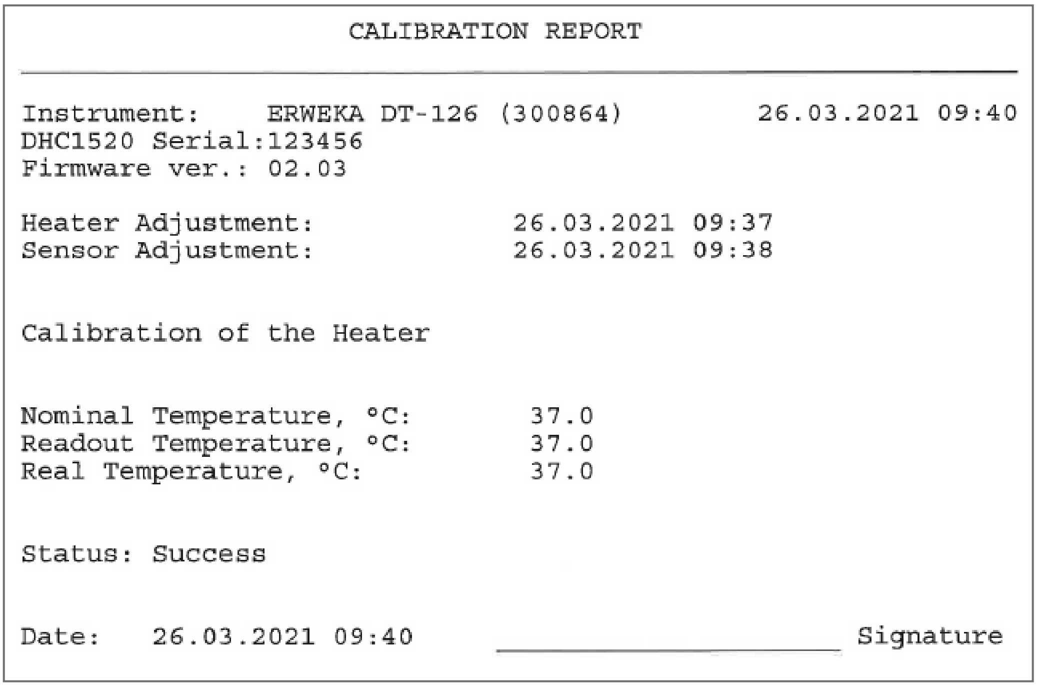
```
                    ADJUSTMENT REPORT
______________________________________________________________

Instrument:    ERWEKA DT-126 (300864)       26.03.2021 09:38
DHC1520 Serial:123456
Firmware ver.: 02.03


Adjustment of External sensor



P.1, Actual Temp.:    37.0°C
P.1, Real Temp.:      37.0°C


Status: Success


Date:   26.03.2021 09:38    _____________________ Signature
```



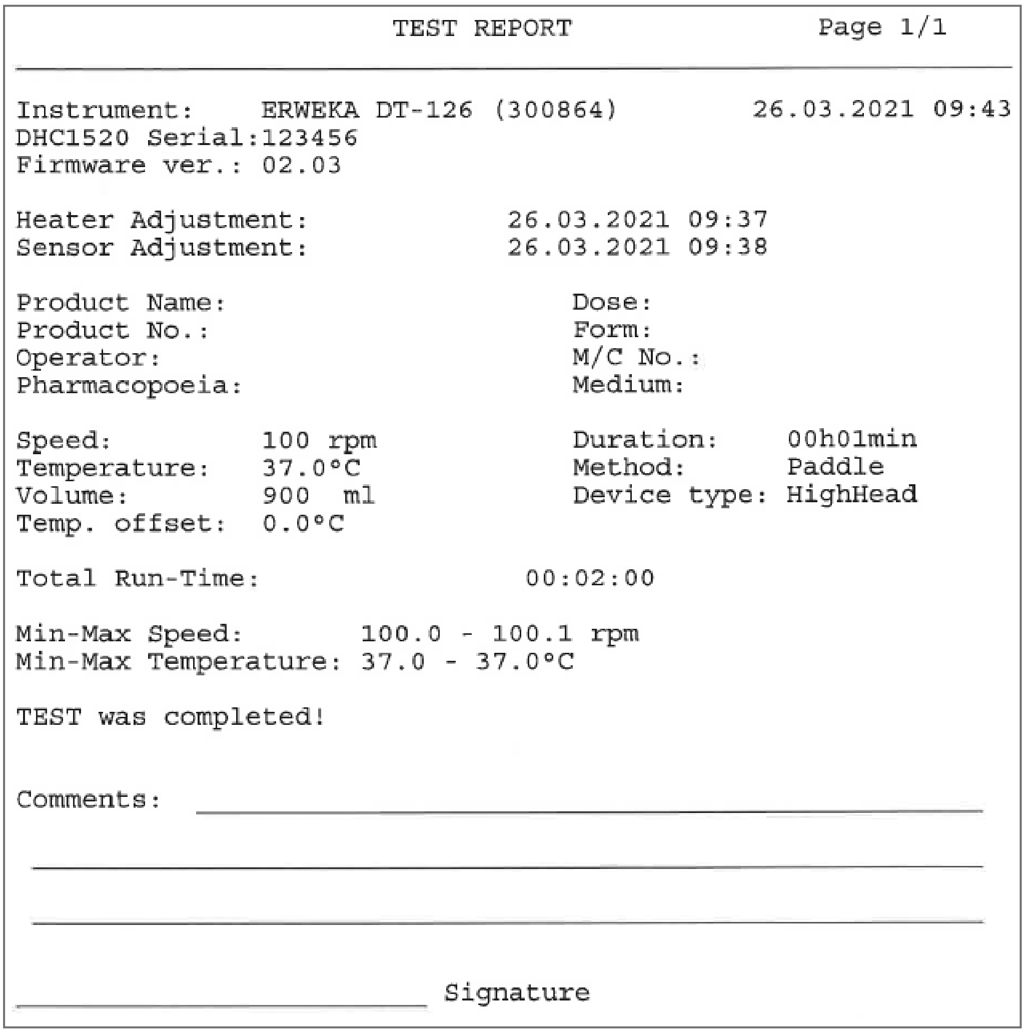
```
                    ADJUSTMENT REPORT
______________________________________________________________

Instrument:    ERWEKA DT-126 (300864)       26.03.2021 09:37
DHC1520 Serial:123456
Firmware ver.: 02.03


Adjustment of the Heater



P.1, Actual Temp.:    37.0°C
P.1, Real Temp.:      37.0°C


Status: Success


Date:   26.03.2021 09:37    _____________________ Signature
```



```
                      CALIBRATION REPORT
______________________________________________________________

Instrument:    ERWEKA DT-126 (300864)        26.03.2021 09:39
DHC1520 Serial:123456
Firmware ver.: 02.03

Heater Adjustment:            26.03.2021 09:37
Sensor Adjustment:            26.03.2021 09:38


Calibration of External sensor


Nominal Temperature, °C:       37.0
Readout Temperature, °C:       36.9
Real Temperature, °C:          37.0


Status: Success


Date:    26.03.2021 09:39     _____________________  Signature
```



```
                      CALIBRATION REPORT
______________________________________________________________

Instrument:    ERWEKA DT-126 (300864)        26.03.2021 09:40
DHC1520 Serial:123456
Firmware ver.: 02.03

Heater Adjustment:            26.03.2021 09:37
Sensor Adjustment:            26.03.2021 09:38


Calibration of the Heater


Nominal Temperature, °C:       37.0
Readout Temperature, °C:       37.0
Real Temperature, °C:          37.0


Status: Success


Date:    26.03.2021 09:40     _____________________  Signature
```



```
                     TEST REPORT                Page 1/1
_____________________________________________________________

Instrument:    ERWEKA DT-126 (300864)       26.03.2021 09:43
DHC1520 Serial:123456
Firmware ver.: 02.03

Heater Adjustment:             26.03.2021 09:37
Sensor Adjustment:             26.03.2021 09:38

Product Name:                      Dose:
Product No.:                       Form:
Operator:                          M/C No.:
Pharmacopoeia:                     Medium:

Speed:         100 rpm             Duration:     00h01min
Temperature:   37.0°C              Method:       Paddle
Volume:        900  ml             Device type:  HighHead
Temp. offset:  0.0°C

Total Run-Time:                 00:02:00

Min-Max Speed:       100.0 - 100.1 rpm
Min-Max Temperature: 37.0 - 37.0°C

TEST was completed!


Comments:  ________________________________________________

 __________________________________________________________

 __________________________________________________________


_________________________  Signature
```

Terminology list

Notion/Abbreviation	Explanation
Basket	Defined sample container (metal basket)
DAB	German Pharmacopoeia (Deutsches Arzneibuch)
Display	LC or LED display
Dissolution test	Dissolution test, test of formulation dissolution in certain media under specified conditions
EP	European Pharmacopoeia
High Head	Upper positioning of the dissolution tester‘s head
Adjustment	Configuration or alignment of the measurement device to eliminate deviations as much as it is required for the foreseen application (in the text the corresponding menu name is applied as notion for convenience)
Calibration	Verification through comparison with reference or traceable standard that a definite device or device produces an appropriate range of measurement results within specific limits (in the text the corresponding menu name is applied as notion for convenience)
LC	Liquid crystal
LED	light-emitting diode
Medium	Fluid environment in the test vessel to dissolve the product
Method	A set of defined conditions, methods and techniques for testing a product
Paddle	Defined tool, blade stirrer
PT 100	A temperature measurement sensor, here used as external temperature sensor, e.g. for measuring water bath or medium temperature
USP	U.S. Pharmacopeial Convention
Vessel	Test container, beaker
Vial	Small test container in autosampler

Contents of the Declaration of Conformity

Certificate of Compliance

We, ERWEKA GmbH, declare under our sole responsibility that the product DT light Series – DH 1520, to which this declaration relates is in conformity with the following EU-Directives and harmonized standards:

- Machinery Directive 2006 / 42 / EC
- Safety of machinery – General principles for design – Risk assessment and risk reduction; EN 12100:2010
- Low Voltage Directive (LVD) 2014 / 35 / EU
- Safety requirements for electrical equipment for measurement, control and laboratory use; EN 61010-1
- Electromagnetic Compatibility, (EMC) Directive 2014 / 30 / EU
- Electrical equipment for measurement, control and laboratory use; EN 61326-1

Langen, 2020-03-06, signed Claudia Müller – Managing Director –

ERWEKA

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